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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Ryszard M. Lec

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EXAMINER

TOTH, KAREN E

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/826,567	Applicant(s) LEC ET AL.	
	Examiner KAREN E. TOTH	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-51 is/are pending in the application.
- 4a) Of the above claim(s) 17-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/16/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

2. Claims 33-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The amendment to claim 33 of “biological sensing media” to “biological substance” appears to be an attempt to overcome the 112 2nd rejection presented in the prior Office Action. However, this amendment results in a significant broadening of the limitation, and does not define what appears to be intended - that is, a biologically active substance. The broadest reasonable interpretation of "biological substance" covers any organic substance, which is quite different than the functional materials described in the specification (see paragraphs [0060], [0066], etc.). Further, there is no support for such a broad limitation.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 33 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim includes the limitation “an inlet port that directs

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blood". The human body may not be claimed; the Examiner suggests amending this to read "an inlet port configured to direct blood". For the purposes of examination it will be treated as such.

Claim Rejections - 35 USC § 102

4. Claims 33, 36, 43, 48, and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Deluca (US 6508104).

Regarding claim 33, Deluca discloses a blood analysis device comprising a transducer element (element 340 or 346), a biological substance in communication with the transducer (the blood that is undergoing analysis - column 3, lines 39-45), a signal driver in communication with the transducer element that applies a varying signal to the element (elements 48, 346; column 16, lines 3-18), an inlet port directing blood to the transducer (sample tubes 25), and a signal processor in communication with the transducer element that measure's the blood's response to the signal applied by the transducer and uses the measured response to determine a characteristic of the blood (elements 38, 44).

Regarding claim 36, since Deluca's biological substance is blood its presence inherently facilitates determination of one of its characteristics.

Regarding claim 43, Deluca's device may be used to test any subject's blood, including that of the person operating the unit.

Regarding claim 48, Deluca further discloses data storage, data processing, and data transmission (column 10, lines 6-16).

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Regarding claim 49, Deluca further discloses storing temperature data (column 10, lines 16-20).

5. Claims 33-35, 37, 39, and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Herrmann (US 6543274).

Regarding claims 33 and 37, Herrmann discloses a blood analysis device comprising a transducer element (elements 5, 6), a biological substance in communication with the transducer (the blood that is undergoing analysis – 1, lines 30-36), a signal driver in communication with the transducer element that applies a varying frequency signal to the element (column 5, lines 31-50), an inlet port directing blood to the transducer (element 2), and a signal processor in communication with the transducer element that measure's the blood's response to the signal applied by the transducer and uses the measured response to determine a characteristic of the blood (column 8, lines 13-65).

Regarding claims 34 and 35, Herrmann further discloses the transducer element comprising an array of piezoelectric sensors (column 3, lines 54-66).

Regarding claim 39, the Examiner notes that there are no alternatives to individual, sequential, and simultaneous deliveries of a signal, and Herrmann's signal therefore inherently is delivered via one of these options.

Regarding claim 40, Herrmann further discloses including resonant frequencies (column 6, lines 45-52).

Claim Rejections - 35 USC § 103

6. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Deluca in view of Kensey (US 2001/0044584).

Deluca discloses all the elements of the claimed invention, as described above, except for a catheter in communication with the transducer. Deluca does not describe how the blood sample is obtained. Kensey teaches a system for analyzing blood characteristics using a catheter to obtain a blood sample to which a signal is applied (paragraph [0126]), in order to obtain a blood sample with minimal discomfort to the patient. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Deluca with a catheter in communication with the transducer, as taught by Kensey, since catheters are well known in the art for obtaining blood samples and Deluca did not disclose how to obtain a sample for analysis.

7. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Deluca in view of Jina (US Patent 6673622).

Ringrose discloses all the elements of the claimed invention, as described above, except for the device providing information to a patient. Jina teaches a blood characteristic analysis system comprising data storage, processing, and transmission, including storing blood data and providing information to a patient via a display (column 6 line 30 to column 7 line 23), in order to effectively analyze and use the gathered data. It would have been obvious to one of ordinary skill in the art at the time the invention

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was made to have configured the system of Deluca to transmit medical condition information to a patient, as taught by Jina, in order to effectively analyze and use the gathered data.

8. Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Deluca in view of Stiene (US Patent Application Publication 2004/0072357).

Deluca discloses all the elements of the claimed invention, as described above, and further discloses wired and wireless communication, but does not disclose the communication being between the device, a patient, and a medical health center. Stiene teaches a blood characteristic analysis system comprising data transmission, including wired and wireless communication, between the device, a patient, and a health center (paragraphs [0044], [0055]-[0066], [0078], [0115]), in order to facilitate analysis of gathered data and treatment of the patient being analyzed. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have configured the device of Deluca to communicate between the device, a patient, and a medical health center, as taught by Stiene, in order to facilitate data analysis and patient treatment.

Allowable Subject Matter

9. Claims 38, 41, and 44-47 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

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The prior art of record fails to anticipate or make obvious the invention of claim 38, including, *inter-alia*, a blood analysis device comprising a transducer element, a biological substance in communication with the transducer, a signal driver that applies a signal of varying frequency in the range of 1 KHz to 10 GHz, an inlet port for directing blood to the transducer, and a signal processor that measures the blood's response to the applied signal and uses the response to determine a characteristic of the blood.

The prior art of record fails to anticipate or make obvious the invention of claim 41, including, *inter-alia*, a blood analysis device comprising a transducer element, a biological substance in communication with the transducer, a signal driver that applies a varying signal to the transducer, an inlet port for directing blood to the transducer, and a signal processor that measures the blood's response to the applied signal and uses the response to determine a characteristic of the blood, where the transducer creates an effect in the blood sample between 1 nm and 1 cm from the surface of the transducer.

The prior art of record fails to anticipate or make obvious the invention of claim 44, including, *inter-alia*, a blood analysis device comprising two acoustic sensors, one for analyzing the blood and the other for comparing the blood to a reference fluid.

The prior art of record fails to anticipate or make obvious the inventions of claim 45, including, *inter-alia*, a blood analysis device coated with collagen that applies a varying frequency to determine platelet adhesion at a higher frequency and coagulation at a lower frequency.

The prior art of record fails to anticipate or make obvious the inventions of claim 46, including, *inter-alia*, a blood analysis device coated with tissue thromboplastin that

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applies a varying frequency to detect blood coagulation at a lower frequency and at a higher frequency detects plasma coagulation factor concentration and/or activation.

The prior art of record fails to anticipate or make obvious the invention of claim 47, including, *inter-alia*, a blood analysis device comprising a transducer element, a biological substance in communication with the transducer, a bulk bioactive material for facilitating determination of a blood characteristic, a signal driver that applies a varying signal to the transducer, an inlet port for directing blood to the transducer, and a signal processor that measures the blood's response to the applied signal and uses the response to determine a characteristic of the blood.

Response to Arguments

10. Applicant's arguments with respect to claims 33-51 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 6311549 to Thundat, US 2002/0124634 to Litton, 2004/0214337 to Kautzky, 2002/0007665 to Miura, 5306644 to Myerholtz, 2004/0216515 to Yahkno, US 4558589 to Hemmes, and 2005/0212869 to Ellzon, which disclose similar inventions.

Collings (US 5952560) discloses a similar system that uses a transducer to apply a signal to blood and uses the blood's response to the applied signal to determine a

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characteristic, but Collings does not disclose a biological substance in communication with the transducer.

Ringrose (US 4149405) discloses a similar blood analysis system that a transducer to apply a signal to blood and uses the blood's response to the applied signal to determine a characteristic, but Ringrose performs the analysis upon a single droplet, which must be placed on a flat surface for the invention to work properly, rather than a structure reached via a port.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAREN E. TOTH whose telephone number is (571)272-6824. The examiner can normally be reached on Mon thru Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patricia C. Mallari/
Primary Examiner, Art Unit 3735

/K. E. T./
Examiner, Art Unit 3735